

AUG 08 2002

Sheath Adapter

Special 510(k)

SECTION 3. 510(K) SUMMARY

Submitter:	ARROW International, Inc. 2400 Bernville Road Reading, PA 19605-9607 USA
Contact person:	Brandon Epting Regulatory Associate Phone: 610-378-0131, ext. 3498 Fax: 610-374-5360 Email: brandon.epting@arrowintl.com
Date summary prepared:	May 20, 2002
Device trade name:	Sheath Adapter
Device common name:	Sheath Adapter
Device classification name:	Catheter Introducer
Legally marketed devices to which the device is substantially equivalent:	Arrow Percutaneous Sheath Introducer (K780532) Thomas Medical Products Tuohy-Borst Adapter (K904608)
Description of the device:	The proposed device is an accessory to Arrow's existing Percutaneous Sheath Introducer (PSI) (K780532). The adapter is attached to the hemostasis valve of the sheath introducer allowing a broader range of device sizes to be placed through the introducer.
Intended use of the device:	When attached to the hub of the PSI, a hemostasis valve in the sheath adapter device permits the insertion of a 4 Fr to 7 Fr catheter through the PSI and prevents leaking and bleedback. The Tuohy-Borst mechanism in the sheath adapter can be tightened to prevent catheter migration and to prevent leakage and bleedback.
Technological characteristics:	The proposed sheath adapter has the same technological characteristics as the predicate devices.
Performance tests:	Tests were performed to demonstrate substantial equivalence in the following areas: <ul style="list-style-type: none">• Leak resistance• Insertion / drag force• Cap torsion
Conclusions:	The results of the laboratory tests demonstrate that the device is as safe and effective as the legally marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 08 2002

Arrow International, Inc.
c/o Mr. Brandon Epting
Regulatory Affairs Associate
2400 Bernville Road
Reading, PA 19605

Re: K021723

Trade Name: Sheath Adapter
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer, Catheter
Regulatory Class: Class II (two)
Product Code: DYB
Dated: July 25, 2002
Received: July 26, 2002

Dear Mr. Epting:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Donna-Bea Tillman", written in a cursive style.

Donna-Bea Tillman, Ph.D.

Acting Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 7: INDICATIONS FOR USE STATEMENT

Page ____ of ____

510(k) Number:

K021723

Device Name:

Sheath Adapter

Indications for Use:

The Arrow Sheath Adapter is utilized in conjunction with one-piece Percutaneous Sheath Introducer to permit venous access and catheter introduction into the central circulation.

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division of Cardiovascular & Respiratory Devices
510(k) Number K021723

Prescription Use X
(Per 21 CFR 801.109)